EXHIBIT C

U.S. FOOD & DRUG ADMINISTRATION

Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

June 7, 2019

Via Email

John C. Bostic
Assistant United States Attorney
U.S. Attorney's Office
Heritage Bank Building
150 Almaden Blvd. Suite 900
San Jose, CA 95113

Re: Document Access Request – *United States v. Elizabeth Holmes & Ramesh Balwani*, 18-CR-00258 EJD (N.D. Cal.)

Dear Mr. Bostic:

This letter responds to your letter dated May 9, 2019, addressed to Lauren DiPaola, Lead Testimony Specialist at the U.S. Food and Drug Administration ("FDA"), which seeks documents and information in FDA's possession in response to requests made by the Defendants in the above-referenced action, Elizabeth Holmes ("Holmes") and Ramesh Balwani ("Balwani"). Specifically, your letter seeks access to six categories of documents, including communications, correspondence, notes, or recordings (hereinafter, "documents") relating generally to Theranos, Inc. ("Theranos") and (1) the Wall Street Journal and John Carreyrou, (2) Clinical Laboratory Improvement Amendment ("CLIA") compliance, (3) clinical laboratories, (4) FDA's determination of the type of approval required for Theranos' devices, (5) interviews with witnesses, and (6) the 2013 CLIA survey. Your request does not contain any date limitations.

As an initial matter, we do not expect FDA to have many responsive documents to categories (2) and (6), because the CLIA Program is implemented by the Centers for Medicare & Medicaid Services ("CMS"), not FDA. *See generally* 42 C.F.R. Part 493. Moreover, as you know, the Department of Justice ("DOJ") previously received from FDA and/or the Securities and Exchange Commission ("SEC") a significant number of FDA documents—over 40,000 pages—relating to Theranos, which DOJ has already provided to the Defendants. Def. Holmes Mot. to Compel, Dkt. #67, at 3 in *United States v. Holmes, et al.*; *see also id.* at 13 (describing DOJ's production of documents originally sourced from FDA as "substantial"); *see also* Def. Balwani's Joinder in Holmes Mot. to Compel, Dkt. #68. We also understand that DOJ has already provided to Defendants all of FDA's witness interviews related to this matter, which are responsive to category (5) of your request, and we do not expect that the agency will have additional documents to produce in this category.

As you also know, the Superseding Indictment against Defendants alleges wire fraud and conspiracy to commit wire fraud against doctors and Theranos' patients and investors.

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The only allegation that mentions FDA states that Defendants "represented to investors that Theranos did not need [FDA] to approve its proprietary analyzer and tests, but instead that Theranos was applying for FDA approval voluntarily because it was the 'gold standard'; when, in truth, *[Defendants] knew that by late 2013 and throughout 2014, the FDA was requiring Theranos to apply for clearance or approval for its analyzer and tests*." Superseding Indictment, Dkt. #39, at 5, ¶ 12(F) (emphasis added). It seems, then, that the only documents that you are now requesting that are potentially relevant to this case are documents in category (4), which relate to what FDA told Defendants in late 2013 and throughout 2014 regarding the type of FDA approval or clearance required for Theranos' devices. Documents in the remaining categories are not relevant to the issues in your case.

Prior to receiving your letter, FDA was served with a subpoena (initially issued on September 12, 2018, and "reissued" on March 15, 2019) in *SEC v. Balwani*, Case No. 18-cv-01603-EJD (N.D. Cal.), the civil case brought by the SEC against Balwani. The subpoena requests 20 broad categories of documents referring or relating to Theranos, Holmes, and Balwani, from the 8½-year period from January 2010 through June 2018. The documents requested by your letter comprise a subset of the documents that are responsive to the subpoena.

To respond to the subpoena, FDA has already searched the records of at least 45 custodians, including both current and former FDA employees, and has collected in excess of 62,000 documents that contain the keywords for which we searched.[1] The agency is in the process of reviewing those documents for responsiveness and, for those that are responsive, conducting a page-by-page, line-by-line review for privilege and other protections, as more fully laid out below. **As we process the documents for the subpoena, we will provide documents to you, including those that are responsive to the six categories you have requested, with certain exceptions as set forth below.**

Please be aware that FDA does not currently have an automated method for identifying duplicates in the newly-collected documents, nor does it currently have an automated way to compare the newly-collected documents to the previously-produced documents. We are working with our information technology staff to make our review more efficient; however, at present, we need to manually compare the newly-collected documents to identify and remove duplicates, including lesser-included duplicates (such as a less complete email string). To the extent that FDA obtains an automated mechanism that would permit us to compare the newly-collected documents with the previously-produced documents, we will not re-produce any FDA documents already provided to Holmes and Balwani by DOJ.

[1] This is a document count, not a page count, and FDA has not completed inventorying all collected documents to count attachments separately. Accordingly, this number is an approximation of the minimum number of documents collected; the actual number likely will be significantly higher.

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FDA also will not produce any automated emails sent to agency employees from public media or other organizations including, but not limited to, Bulletin Intelligence, GenomeWeb, The Gray Sheet, PharmaVOICE, POLITICO Pulse, and Google Alerts, which emails solely contain links to publicly-available information about Theranos. FDA will, however, provide any such emails that FDA employees forwarded with comment.

Before FDA can provide any documents in response to the subpoena and your request, we need to redact privileged and otherwise confidential information from the newly-collected documents. FDA is prohibited from releasing trade secret information obtained under certain of its regulatory authorities in judicial proceedings that are not brought under the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. § 331(j). FDA is also prohibited from releasing trade secret and confidential commercial or financial information ("CCI") regarding certain devices obtained through the agency's regulatory and inspectional authorities. 21 U.S.C. § 360j(c). The Trade Secrets Act, 18 U.S.C. § 1905, also prohibits FDA from releasing trade secrets and CCI unless otherwise authorized by law. And, FDA regulations provide that trade secrets and CCI are not available for public disclosure. *See* 21 C.F.R. § 20.61. Many of the documents that are responsive to the subpoena and your request contain Theranos' trade secrets and CCI and may also contain third-party trade secrets and CCI. FDA cannot lawfully produce any responsive documents that would reveal such information absent a court order or a waiver permitting FDA to release such information in response to your request.[2] If the Theranos assignee provides a written waiver permitting FDA to release its trade secrets and CCI in response to the subpoena and your request, which we understand may be forthcoming, it would facilitate a quicker review and would result in the documents being less redacted and of more utility.

However, even if FDA receives a waiver from the Theranos assignee, the agency stills need to review and redact from the newly-collected documents third-party trade secrets and CCI, as well as privileged and otherwise-protected information, including attorney-client communications, attorney work product, personal privacy information, privileged investigatory files, privileged deliberative process, and/or other protected information. *See* 21 C.F.R. §§ 20.62–.67, 20.85. FDA will also redact all non-responsive information from the newly-collected documents. For example, there are documents from FDA's media staff that reference all open press inquiries and CDRH documents that reference all pending CDRH matters; FDA will redact as unresponsive all information unrelated to Theranos but will leave in any non-privileged information regarding Theranos.

In addition, because the subpoena and your request seek documents that have already been reviewed, redacted, and released publicly pursuant to the Freedom of Information

[2] To the extent DOJ and/or Defendants already possess FDA documents from which Theranos's trade secrets or CCI were not redacted, such productions were made pursuant to waivers from Theranos permitting FDA to provide the information to DOJ and SEC and permitting DOJ to give the FDA documents to the Defendants. To date, the Theranos assignee has not provided a waiver for FDA to release its trade secret and CCI in the newly-collected documents.

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Act ("FOIA") and for which subsequent review and redaction would constitute needless and/or burdensome duplication of time and effort, any responsive documents that have already been redacted will not be re-reviewed and, instead, will be provided as they were released to the public previously. Finally, FDA is limiting its search and production in response to your request to the time frame set forth in the subpoena, January 2010 through June 2018.

It will take a significant amount of FDA employee time to prepare and produce the documents responsive to the subpoena and your request. Although we cannot currently predict how much time it will take to review and process the newly-collected documents, we can begin producing documents to you on a rolling basis within one month.

FDA is committed to producing documents in a manner consistent with federal law and agency procedures. The agency has already expended a significant amount of resources to respond to document requests in connection with your criminal investigation of Defendants, SEC's civil investigation of Defendants, and Mr. Balwani's subpoena in the SEC civil action pending against him, and will continue to produce additional responsive, non-privileged documents consistent with the foregoing objections in response to your request.

If you have any further questions, please contact me at 301-796-8580.

Sincerely,

Marci B. Norton

Marci B. Norton
Senior Counsel